

CLAIMS

1. Therapeutic system for the controlled release of one or more active ingredients, with previously programmed passage, characterised by the fact that it comprises a nucleus constituted of a three layered tablet of which the two external layers vehicularise the active ingredient(s) whilst the internal layer is constituted of a polymeric barrier erodible or gelable in aqueous means, said tablet being completely coated by a film of polymeric material insoluble in aqueous fluids, on which have been carried out by laser one or more incisions delimiting an area of geometric shape and predetermined dimensions as a function of the release times which it is desired to obtain, said release taking place from the area of the nucleus underlying the surfaces of the film coating delimited by the incisions, which are detached when the therapeutic system comes into contact with aqueous fluids.
2. Therapeutic system according to claim 1, in which the coating film is incised only in correspondence with the first layer of the tablet (nucleus).
3. Therapeutic system according to claim 1, in which the film coating is incised in correspondence both with the first and the third layer.
4. Therapeutic system according to claim 2, in which both the first and the third layer comprise the same active ingredient.
5. Therapeutic system according to claim 2, in which the first and the third layer comprise different active ingredients.
6. Therapeutic system according to claim 3, in which the first and the third layer comprise different active ingredients.
7. Therapeutic system according to claim 1, in which the first and the third layer have an identical composition for the controlled release of the active ingredient.
8. Therapeutic system according to claim 1, in which the first and third layer have different compositions for the controlled release of the active ingredient.
9. Therapeutic system according to claim 1, in which the area delimited by the incision(s) on the insoluble coating film has dimensions comprised of between 2 and 50% of the total area of the coating.
10. Therapeutic system according to claim 9, in which the area delimited by the incision(s) on the insoluble coating film is of dimensions comprised of between 5 and 30% of the total area of the coating.

11. Therapeutic system according to claim 1, in which the first layer comprises one or more polymers able to modulate the release of the active ingredient.
12. Therapeutic system according to claim 11, in which said polymers constitute between 1% and 90% in weight of said layer.
13. Therapeutic system according to claim 12, in which said polymers constitute between 5% and 60% in weight of said layer.
14. Therapeutic system according to claim 1, in which the first layer comprises excipients capable of accelerating the release of the active ingredient(s).
15. Therapeutic system according to claim 14, in which said excipients are disintegrants or effervescent mixtures.
16. Therapeutic system according to claim 1, in which the third layer comprises one or more polymers capable of modulating the release of the active ingredient(s).
17. Therapeutic system according to claim 16, in which said polymers constitute between 1% and 90% in weight of said layer.
18. Therapeutic system according to claim 17, in which said polymers constitute between 5% and 60% in weight of said layer.
19. Therapeutic system according to claim 1, in which the third layer comprises excipients able to accelerate the release of the active ingredient.
20. Therapeutic system according to claim 19, in which said excipients are disaggregants or effervescent mixtures.
21. Therapeutic system according to claim 1, in which the second layer comprises one or more polymers selected from predominantly erodible polymers and predominantly gelifiable polymers.
22. Therapeutic system according to claim 21, in which said polymers constitute between 5 and 90% in weight of said layer.
23. Therapeutic system according to claim 22, in which said polymers constitute from 30 to 90% in weight of said layer.
24. Therapeutic system according to claim 1, in which said three layers each have a thickness comprised of between 0.5 and 5 mm.
25. Therapeutic system according to claim 1, in which on the insoluble polymeric coating film a second gastroresistant and enterosoluble polymeric coating film is

applied.

26. Process for the preparation of the therapeutic system according to claim 1, characterised by the fact that the incision(s) on the coating film are performed by the use of a laser beam.

27. Process according to claim 26, in which the incision(s) on the coating film are performed with a CO₂ source laser device having an output of 20 W.